The Ehlers-Danlos syndrome and regional anesthesia.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26445

Source
NTR

Brief title
N/A

Health condition

The Ehlers-Danlos syndrome is a group of rare genetic disorders caused by a defect in collagen synthesis. Several patients from the EDS patient organisation claimed that for them regional and local anesthesia did not work properly. Up to now there is no proof or explenation for this phenomenon.

Sponsors and support

Primary sponsor: N/A

Intervention

Outcome measures

Primary outcome

Analgesia in the region of the ulnar nerve within 60 minutes after application of an ulnar nerve block.This will be demonstrated by increasing stimuli from a neurostimulator. If the subject does not regard 20 mA as painful there is of an adequate block.

Secondary outcome

1. Analgesia from the subcutanous injections and the topical application of EMLA cream;

2. Time of onset of analgesia;

3. Time of end of analgesia;

4. Duration of analgesia.

Study description

Background summary

N/A

Study objective

Locoregional anesthesia does not work as well in patients with the Ehlers-Danlos syndrome as in people who do not have this syndrome.

Study design

N/A

Intervention

1. An ulnar nerve block on the non-dominant arm with 3 ml lidocaine 2%;

2. application of 1.5 gram EMLA-cream on the dorsal side of the contralateral hand, covered with foil;

3. three times a fieldblock of 3 by 3 cm by means of three subcutaneous injections on the dorsal side of the thorax; one with lidocaine 1%, one lidocaine 2% and one with NaCl 0.9%.

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Eligibility criteria

Inclusion criteria

For the Ehlers-Danlos group:

1. people with all types of Ehlers-Danlos except type IV, proven by a geneticist or a comparably qualified person;

2. 18 to 65 years old;

3. informed consent.

For the control group:

All subjects are matched with a patient from the Ehlers-Danlos group for age and sexe.

Exclusion criteria

For Ehlers-Danlos patients:

1. Type IV Ehlers-Danlos;

2. co-existing disease which increases the risk of locoregional anesthesia, according to prudent daily clinical practice;

3. hereditary acquired or drug induced bleeding disorders;

4. periferal mononeuropathy, polyneuropathy, multiple sclerosis or other relevant neurologic disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	50
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL780
NTR-old	NTR791
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A